



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1430
Alexandria, Virginia 22313-1430
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,246	07/24/2003	Christopher J. Elliott	10123/00601	1009

7590 01/25/2008
Patrick J. Fay, Esq.
FAY KAPLUN & MARCIN, LLP
Suite 702
150 Broadway
New York, NY 10038

EXAMINER

HOUSTON, ELIZABETH

ART UNIT	PAPER NUMBER
----------	--------------

3731

MAIL DATE	DELIVERY MODE
-----------	---------------

01/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAILED
JAN 25 2008
GROUP 3700

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/626,246
Filing Date: July 24, 2003
Appellant(s): ELLIOTT, CHRISTOPHER J.

Oleg Kaplun
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/02/07 appealing from the Office action mailed 04/25/07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,287,318	VILLAR ET AL.	11-2001
5,980,514	KUPIECI ET AL.	11-1999

6,171,326

FERRERA ET AL.

01-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5-11, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kupiecki (USPN 5, 980, 514) in view of Villar (USPN 6,287,318).

Kupiecki discloses an embolic coil comprising an elongated core element (Fig 8, 204) formed of a shape memory material, nitinol, (Col 14, line 16) treated to define a memorized secondary coil shape; and an elongated outer element (202) wound around the elongated core element to define a primary coil shape of the embolic coil and formed of platinum (Col 14, line 18). It is inherent that the shape memory material, of which the elongated core element is formed, is in an austenitic phase at an operation temperature of the embolic coil. The secondary coil has a secondary coil memorized shape, wherein, when heated to a temperature above a critical temperature of the shape memory material, the secondary coil causes the primary coil to follow the secondary coil shape (Col 14, lines 33-35).

Kupiecki does not disclose that the coil has fibers.

Villar discloses an embolic coil comprising polymeric fibers, which promote tissue growth by facilitating the formation of scar tissue, healing tissue or neocapillaries in vascular occlusions. Villar discloses that the fibers are looped through the turns of the coils to lower the overall diameter of the device for ease of delivery (Fig. 2, Col4, lines 53-58). This meets the limitation that the fibers are gripped (by the coil that it is looped around) between adjacent coils.

It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the fibers into the coil since they enhance the performance of the coil as stated by Villar. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

Regarding claim 11, Kupiecki in view of Villar discloses the invention substantially as claimed as stated above. However Kupiecki in view of Villar fails to disclose fiber retention grooves. The instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result to the embolic coil. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Regarding claim 5, Kupiecki in view of Villar teaches an outer elongated element with a primary coil shape but is silent as to how the primary shape is formed. The claimed phrase "cold working" is being treated as a Product by Process limitation that is the primary shape of the outer elongated element is formed by cold working. As set

forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (See MPEP § 2113). Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

Thus, even though Kupiecki is silent to the process used to form the cut, it appears that the product disclosed by Kupiecki would be the same or similar as that claimed; especially since both applicant's product and the prior art product has an embolic coil with a core and an outer element and a primary and secondary shape.

NEW GROUND(S) OF REJECTION

Claims 5 (alternatively) and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kupiecki in view of Villar as applied to claim 1 above and further in view of Ferrera (USPN 6,171,326).

Kupiecki in view of Villar discloses all the limitations of the instant invention substantially as claimed as stated above except for applying cold work to the outer element and the elongated outer element comprising a platinum wire co-wound with a shape memory material.

Ferrera discloses an embolic coil that incorporates the use of a multi-stranded micro-cable comprising both shape memory strands and radiopaque strands that can be platinum (Figs. 5 and 6 and Col 6, line 47 – Col 7, line 42). The advantage of using a multi-stranded cable is the relative flexibility and resistance to kinking compared to a single wire resulting in less trauma to surrounding tissue and ease of placement in small body cavities. Ferrara teaches cold working as a way of shaping embolic coils (Col 3, line 63-64).

It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the use of the multi-stranded micro cable into the embolic coil to result in a device where the elongated outer element comprises a platinum wire co-wound with a shape memory material wire. Ferrara provides the motivation stating that the multi-stranded micro-cable resists kinking and is more easily delivered without causing trauma to the tissue. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

As an alternative to the product by process rejection stated above, it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the use of cold working into the formation of the embolic coil since the process of cold working is well known in the art for imparting shape into shape memory material as disclosed by Ferrara. The inventions are analogous with each other and the instant invention and therefore the combination is proper. Therefore, even if "cold working" results in different structural characteristics of the end product than other methods, it still would have been *prima facie* obvious at the time the invention was

made to use “cold working” in Kupiecki as claimed since Ferrera teaches that “cold working” is recognized as a useful technique for forming embolic coil shapes.

(10) Response to Argument

Appellant continues to maintain that Villar does not provide the missing limitation “a plurality of fibers *gripped between* adjacent coils of the primary coil” when combined with Kupiecki. The foundation for appellant’s argument is based on what is intended by the term grip. Upon examination of the specification, there is no special definition given to the term grip or gripped. In fact, this term is not even found in the specification. The closest interpretation of the limitation “gripped” can be found in the specification (Para [0012]) where it states, “The fibers 22 may be held in place, for example, by friction between the loops of the primary coil, such that a certain amount of pressure between the loops is necessary to securely retain the fibers 22 therebetween.”

Although the specification uses terminology such as “friction” and “pressure between the loops”, there is no use of this terminology in the claims. Since the limitations from the specification are not relied upon, it is the language itself of the claims (i.e. gripped), which must particularly point out and distinctly claim the subject matter, which the appellant regards as his invention, without limitations imported from the specification, whether such language is couched in terms of means plus function or consists of a detailed recitation of the inventive matter. Limitations in the specification

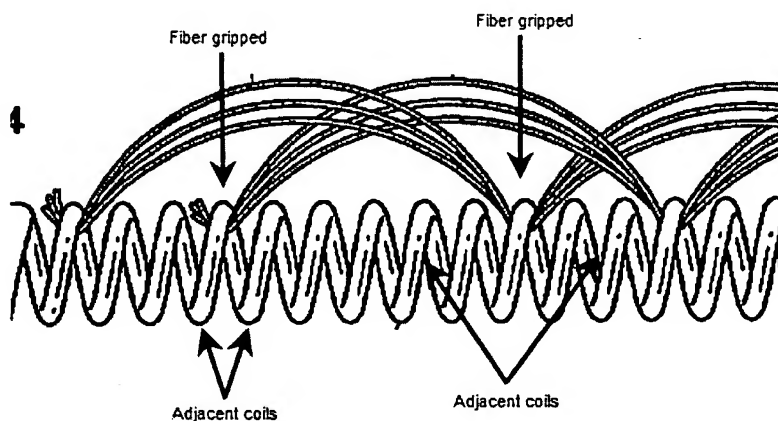
not included in the claim *may not be relied upon* to impart patentability to an otherwise unpatentable claim. In re Lundberg, 113 USPQ 530 (CCPA 1957).

With no clear definition given in the specification, the words of the claim must be given their plain meaning. In other words, claims in a pending application should be given their *broadest reasonable interpretation* consistent with the specification (See MPEP Chapter 2111). Therefore, one must look to the dictionary for further clarification of the term "gripped". Appellant thoughtfully provides a dictionary definition for the term "gripped" as "*secure and maintain tight hold on; seize firmly*". This definition is applied to the Villar reference to draw the conclusion that the primary coil would not be able to "secure and maintain a tight hold" on the fibers between its adjacent coils since the coils in the Villar reference are not tightly wound. However, another definition provided by examiner in the remarks of the final office action (04/25/07), defines "grip" as "*A manner of grasping and holding*" according to *The American Heritage® Dictionary of the English Language, Fourth Edition*. It is certain that, of the two definitions, the latter would be the considered the *broadest reasonable interpretation* of the term "gripped". In conclusion, examiner asserts that Villar, regardless of how the fibers are secured or attached to the coil, does in fact teach that the fibers are "grasped and held" (i.e. gripped) by the coil at each of the multiple points of contact with the coil.

Appellant goes on to argue that the fibers are attached to the core member by glues or by heating. Examiner asserts that this argument actually provides support for the examiner's case. If the fibers are in fact are attached, regardless of how, would they

not be "gripped" as by the appellants previously recited definition (*secure and maintain a tight hold on; seize firmly*)?

Finally, appellant argues that the attachment would exist only at the point where the fiber touches the core wire, which is not *between* the adjacent coils. However the claims are not so limiting as to require that the *point* of contact or attachment between the fiber and the coil is at a location *between* the adjacent coils. The claim merely requires that the gripping exists between adjacent coils as is shown below. (Note that adjacent does not require that the coils be directly next to each other but merely near each other.)



Regarding claim 12, examiner respectfully acknowledges that a reference was inadvertently omitted from the rejection. The rejection statement should have been recited as: **Claims 5 (alternatively) and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kupiecki in view of Villar as applied to claim 1 above and further in view of Ferrera (USPN 6,171,326).** Since claim 12 was dependent from claim 1, it should have been clear that the rejection of claim 12 would have required the

same combination of Kupiecki and Villar as it was applied to claim 1. The feature taught by Ferrera of an elongated outer element comprising a platinum coil co-wound with a wire formed of shape memory could have just as easily been applied to the combination of Kupiecki modified by Villar as it was to Kupiecki alone. The body of the rejection and the motivation for combination would not have changed and therefore this oversight does not wholly affect the grounds of rejection to be reviewed on appeal.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section (9) above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte dismissal of the appeal* as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

Elizabeth Houston

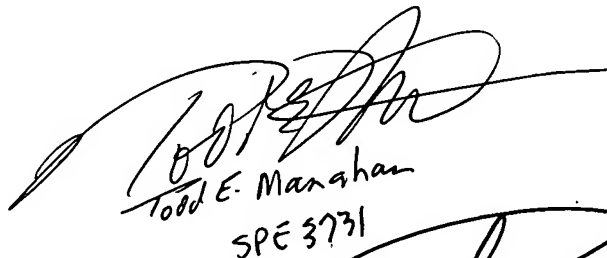


A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

Fred Schmidt

Conferees:

Todd Manahan



Todd E. Manahan
SPE 3731

Tatyana Zalukaeva



TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

FREDERICK R. SCHMIDT
DIRECTOR
TECHNOLOGY CENTER 3700